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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,562	09/16/2003	Nina Rautonen	17031	2985

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EXAMINER	
BLAND, LAYLA D	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,562	RAUTONEN ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-14,16-20,24,26-28,30 and 32-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-14,16-20,24,26-28,30 and 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25, 2008 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed November 25, 2008, and amendment and response to the Final Office Action (mailed July 25, 2008), filed November 25, 2008, wherein claims 1, 5, 8-13, 16, 32, and 33 are amended, and supplemental amendment submitted December 1, 2008, wherein claims 35 and 36 are newly submitted.

Claims 1, 5-14, 16-20, 24, 26-28, 30, and 32-36 are pending and are examined on the merits herein.

Specification

The disclosure is objected to because of the following: Examples 2 and 3 on pages 20-22 of the specification refer to Figures, but no figures are present in the application.

Appropriate correction is required.

The following are new rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-14, 16-20, 24, 26-28, 30, and 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (and dependent claims) recites the limitation "subject suffering from uncontrolled accumulation of lactic acid in the colon." It is unclear what "uncontrolled accumulation of lactic acid in the colon" means and thus unclear which subjects suffer from it. It is known that lactic acid is a metabolite from fermentation in the colon, but it is unclear how much lactic acid is required to be "uncontrolled." The specification, page 10, defines "controlled" to mean that energy is released evenly throughout the colon without major variations in the amount of available energy for the colon cells. The specification, page 9, states that imbalanced fermentation leads to local exceptionally high or low amounts of metabolites from fermentation, such as lactic acid. Thus, the examiner infers that subjects suffering from uncontrolled accumulation of lactic acid in the colon are those in which energy available for bacteria in the colon is not evenly distributed along the colon. For reasons set forth in previous office actions, these subjects are considered to be any subjects. Thus, for the purposes of examination, "subject suffering from uncontrolled accumulation of lactic acid in the colon" is considered to be any subject.

The following rejections were previously presented and withdrawn when specific foods were added to claim 1. Those foods are no longer present in claim 1 so the rejections are again presented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-14, 16-20, 26-28, 30, and 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Olinger et al. (WO 00/40101, published July 13, 2000, of record).

Olinger et al. teach a dietetic chocolate composition sweetened by a composition which includes 10-90% by weight of maltitol, 9-89% by weight of lactitol and 1-55% by weight of polydextrose [page 4, lines 9-20]. The composition exhibits a surprisingly high degree of sweetness relative to what would be expected from a simple mixture of the sweeteners [page 8, lines 28-31], which shows a synergistic relationship. A specific example [page 12, Table 1, Example 4] gives a composition comprising 12.50% lactitol and 26.50% polydextrose. This is a ratio of roughly 1:2 polyol to polydextrose and therefore meets the limitations of claim 30. Olinger et al. also teach that the composition can be made from purified polydextrose, unpurified polydextrose,

hydrogenated polydextrose or a mixture thereof [claim 20] The dietetic chocolate products were tasted (administered) [page 9, lines 11-19].

The claimed patient population is considered to be anyone, as set forth above. Olinger et al. are silent on the accumulation of lactic acid in the colon. However, it is will known that polydextrose has physiologic effects similar to those of dietary fiber (see Jie et al., as above) and is fermented in the colon; this is an inherent property. Thus, the claims are anticipated by Olinger et al.

Claims 1, 5-13, 19, 27, 28, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Jie et al. (Am J Clin Nutr 2000, 72:1503-9, of record).

Jie et al. teach a study in which 4-12 grams of polydextrose per day were consumed by volunteers in order to study the physiologic effects. The polydextrose used was Litesse, provided by Danisco Cultor [page 1504, first paragraph], which is purified. Fecal pH decreased proportionally to polydextrose intake. Short-chain fatty acid production, notably butyrate, isobutyrate, and acetate, increased with polydextrose ingestion. *Bacteroides* (infection-causing bacteria) species decreased and *Lactobacillus* and *Bifidobacterium* (lactic acid bacteria) species increased. [page 1503, Results] Jie et al. also teach that polydextrose is partially fermented in the large intestine and fermentation of polydextrose leads to diminished putrefactive microflora and suppressed production of carcinogenic metabolites [page 1503, column 2, lines 13-19]. A high fecal output and low bowel pH can suppress the production of enteric

toxins, which plays an important role in the prevention of diverticulosis and reduces the risk of bowel cancer [page 1506, column 2, lines 16-18].

The claimed patient population is considered to be anyone, as set forth above. Jie et al. are silent on the accumulation of lactic acid in the colon. However, it is will known that polydextrose has physiologic effects similar to those of dietary fiber and is fermented in the colon; this is an inherent property. Thus, the claims are anticipated by Jie et al.

Response to Arguments

Applicant argues that the amended claims are drawn to a method of treating a specific disorder – uncontrolled lactic acid accumulation, and that none of the cited references refer to that specific condition. As discussed above, uncontrolled lactic acid accumulation is not specifically defined in the specification and, given the broadest reasonable interpretation of the claims, any subject could be considered to have uncontrolled lactic acid accumulation in the colon.

Applicant argues that Jie teaches that polydextrose caused an increase of bacteria of the genus *Lactobacillus*, which would be expected to provide enhanced lactic acid build-up. However, while Jie teaches increased butyrate, isobutyrate, and acetate, increased lactic acid is not taught.

The following rejections are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5-14, 16-19, 27, 28, 30, and 32-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Takemori et al. (US 5,711,982, January 27, 1998, of record).

Takemori et al. teach a de-lactose milk powder containing polydextrose [column 9, Example 4]. The de-lactose milk powder was used to prepare chocolate, which contained 20.5 parts polydextrose and 14 parts lactitol [column 9, lines 39-47]. The chocolate was administered to a panel of high school students [column 10, lines 26-45]. Thus, the high school students were administered dry milk containing polydextrose, along with lactitol, in a ratio of about 1.5:1.

Takemori is silent regarding the purification of polydextrose, but it is considered very likely that the polydextrose was purified because it was administered to children.

Takemori is silent regarding synergism between polydextrose and lactitol, but the amounts taught by Takemori fall within the preferred ranges given on page 16 of the instant specification.

The claimed patient population is considered to be anyone, as set forth above. Takemori et al. are silent on the accumulation of lactic acid in the colon. However, it is will known that polydextrose has physiologic effects similar to those of dietary fiber and is fermented in the colon; this is an inherent property. Thus, Takemori et al. teach administration of the same composition to the same patient population and the claims are anticipated.

Response to Arguments

Applicant argues that Takemori does not teach how much polydextrose is required to treat uncontrolled lactic acid accumulation. This is an inherent property of polydextrose, as set forth above. It is also noted that the instant specification does not disclose a minimum amount of polydextrose.

Claims 1, 5-14, 16, 17, 19, 24, 26-28, 30, and 32-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Shaw Craig et al. (US 2003/0008843, January 9, 2003, of record).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Shaw Craig et al. teach a method for suppressing the appetite of a mammal, comprising administering xylitol and polydextrose in a ratio of about 1:5 to 5:1 [claim 9]. Yogurt containing xylitol and polydextrose in a 1:1 ratio was administered to human subjects [0077]. Polydextrose or hydrogenated polydextrose which is at least 90% pure is desired [0036-0038].

The claimed patient population is considered to be anyone, as set forth above. Shaw Craig et al. are silent on the accumulation of lactic acid in the colon. However, it is will known that polydextrose has physiologic effects similar to those of dietary fiber and is fermented in the colon; this is an inherent property. Thus, Shaw Craig et al. teach administration of the same composition to the same patient population and the claims are anticipated.

Response to Arguments

Applicant's arguments are the same as those addressed above for the Takemori reference.

Claims 1, 5-13, 19, 27, 28, 35, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Solomons et al. (J. Lab. Clin. Med, May 1985, pages 585-592, PTO-1449 submitted January 10, 2008).

Solomons et al. teach a study in which healthy adults of ages 19-45 years were administered 360 ml of intact milk or hydrolyzed milk containing 18 grams of polydextrose [page 586, Methods]. It is noted that no definition of "aged mammal" has been provided. A 45 year old human is in the second half of his or her lifespan, considering an average human lifespan of about 75-80 years, so he or she could

reasonably be considered aged and claim 20 is anticipated. Solomons et al. are silent regarding whether the polydextrose was purified; however, the polydextrose was administered to humans so it was likely purified.

The claimed patient population is considered to be anyone, as set forth above. Solomons et al. are silent on the accumulation of lactic acid in the colon. However, it is will known that polydextrose has physiologic effects similar to those of dietary fiber and is fermented in the colon; this is an inherent property. Thus, the claims are anticipated by Solomons et al.

Response to Arguments

Applicant's arguments are the same as those addressed above for the Takemori reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jie et al. (Am J Clin Nutr 2000, 72:1503-9, of record).

Jie et al. teach a as set forth above.

Jie et al. do not teach the administration of polydextrose to the subjects recited in claim 20 and do not teach incorporation of polydextrose into a sour milk product.

It would have been obvious to one of ordinary skill in the art to administer polydextrose in a food product to a subject having conditions associated with digestive and bowel health. Jie et al. teach that consumption of polydextrose improved bowel function, softened the feces, improved the ease of defecation, promoted the proliferation of favorable intestinal microflora and decreased the pH of the bowel [page 1508, last paragraph]. The skilled artisan could easily conceive of administering a compound that is useful for digestive and bowel health into a food composition. Thus, it would have been obvious to administer a composition that is useful for digestive and bowel health to subjects having conditions associated with digestive and bowel health, such as celiac disease and food allergy, or other conditions which affect digestive and bowel health.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solomons et al. (J. Lab. Clin. Med, May 1985, pages 585-592, PTO-1449 submitted January 10, 2008) in view of Borden et al. (US 5,601,863, February 11, 1997, of record).

Solomons teaches as set forth above.

Solomons does not teach the use of hydrogenated polydextrose.

Borden et al. teach that polydextrose and hydrogenated polydextrose are both enzyme-resistant and functional equivalents as food additives [columns 1-2 and paragraph bridging columns 6-7].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use hydrogenated polydextrose in the method of Solomons et al. Hydrogenated polydextrose is known as a functional equivalent of polydextrose, having improved properties such as color and flavor.

It is noted that the Borden reference could be used in combination with any of the above references in order to establish that polydextrose and hydrogenated polydextrose are functional equivalents.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-14, 16-20, 24, 26-28, 30, and 32-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

claims 7-9, 11-15, 17-18, 22-26, 28-30, and of copending Application No. 10/341,748. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each are drawn to administration of polydextrose and a polyol. Although the instant claims are drawn to administration to a subject suffering from uncontrolled accumulation of lactic acid in the colon and the claims of copending Application No. 10/341,748 are simply drawn to treatment of a mammal, the patient population in the instant claims could be considered any subject, as set forth above. Thus, the claims of copending Application No. 10/341,748 anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/
Examiner, Art Unit 1623